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09/674,935	12/21/2000	Timothy Raymond Hirst	34407-503	8699

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EXAMINER	
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ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/674,935	HIRST ET AL.	
	Examiner	Art Unit	
	JaNa Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-44,46,47,49-52 and 54-64* is/are pending in the application.

4a) Of the above claim(s) *54-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-44,46,47 and 49-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Vacation of Previous Office action

1. Applicant's request for vacating the last Office Action is persuasive and therefore, the action dated December 5, 2007 has been vacated.

Amendment Entry

2. The amendments filed September 6, 2007 have been entered. Claims 38, 43, 46 and 49 have been amended. Claims 1-37, 45, 48,and 53 have been cancelled. Claims 54-64 have been newly added.

3. Claims 38-44, 46-47, 49-52 and 54-64 are under consideration in this office action.

Response to Arguments

4. Applicant's arguments filed September 6, 2007 have been fully considered but they are not persuasive.

Withdrawal of Rejections

5. The rejection of claims 38-44, 46-47, 49-64 under 35 U.S.C. 112, second paragraph has been withdrawn in view of applicants' amendments and arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 38-39, 43-44, 49, 54-56 and 60-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al., (WO 97/02045 published January 23, 1997).

Claim 38 is drawn to a method of enhancing a lymphocyte mediated or immunoglobulin mediated immune response to a vaccine against an infectious disease, in a mammal in need thereof, wherein the enhancement is compared to a lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone, comprising administering to the mammal a therapeutically effective amount of *Escherichia coli* heat labile enterotoxin B subunit (EtxB), wherein the EtxB is free from whole toxin and is not linked to an antigen and co-administering the vaccine, thereby enhancing the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease compared to the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease after administration of the vaccine alone. Claim 39 is drawn to the EtxB increasing the levels of B and T cell lymphocyte response.

Claim 49 is drawn to a method of enhancing a B and T cell lymphocyte mediated or immunoglobulin mediated immune response to a vaccine against an infectious disease, in a mammal in need thereof, wherein the enhancement is compared to a lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone, comprising administering *Escherichia coli* heat labile enterotoxin B subunit (EtxB) in conjunction with administration of an antigen associated with an infectious disease, wherein the EtxB is free from whole toxin and is not linked to the antigen, to the mammal in an amount which is effective to increase the mammalian subject's levels of B and T cell lymphocyte response to the antigen and co-administering the vaccine, thereby enhancing the B and T cell lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease compared to the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone. Claim 43 is drawn to the vaccine being an antigen.

Claim 54 is drawn to a method of generating a lymphocyte mediated or immunoglobulin mediated immune response, in a mammal in need thereof, comprising administering to the mammal a between 50 and 100 ug of Escherichia coli heat labile enterotoxin B subunit (EtxB), wherein the EtxB is free from whole toxin and an antigenic determinant, wherein the EtxB and antigenic determinant are not linked to form a single active agent. Claim 55 is drawn to the method wherein the EtxB and antigenic determinant are administered to the mammal in need thereof in multiple doses. Claims

44 and 56 are drawn to the EtxB and antigen being administered to the said mammalian subject in an amount which is effective to increase the mammalian subject's levels of B and T cell lymphocyte response to the antigen.

Claim 60 is drawn to a method of enhancing a B and T cell lymphocyte mediated or immunoglobulin mediated immune response, in a mammal in need thereof, comprising administering between 50 and 100 ug of *Escherichia coli* heat labile enterotoxin B subunit (EtxB) in conjunction with administration of an antigenic determinant associated with an infectious disease, wherein the EtxB is free from whole toxin and is not linked to the antigen, and wherein the EtxB and antigenic determinant are not linked to form a single active agent. Claim 61 is drawn to the EtxB and antigenic determinant are administered to the mammal in need thereof in multiple doses.

Williams et al., teach therapeutic agents for use in the treatment of mammalian diseases (page 1, line 35 – page 2, line 2). The basis of the invention is that the pure B-subunit of *E.coli* heat labile enterotoxin (ExtB) binds to receptors found on the surface of mammalian cells and this binding induces differential immune response effects on lymphocytes including activation of B and T cells (page 2, lines 1-5). The acronym ExtB means the pure B subunit of *E.coli* heat labile enterotoxin (page 1, lines 34-36). Williams et al., teach separate administration of the therapeutic agent, which is ExtB and the antigenic determinant, thereby teaching separate administration of the moieties (pages 3-4, lines 5-3). Williams et al., teach the ExtB as a vaccine carrier because of its ability to modulate lymphocyte populations (page 10, lines 9-13). Williams et al., teach the agent is capable of modulating the immune response when delivered together with

an unrelated foreign antigenic determinant and the antigen and agent are delivered together as separate moieties (page 10, lines 22-33). Williams et al., teach co-administration and separate administration which occur at the same time (page 8, lines 7-13). Williams et al., teach that the wild type and mutant forms of ExtB have binding capabilities and are known as immunomodulators (page 11, line 31- page 12, line 5). Williams et al., teach the administration of EtxB or ExtB mutants to mice (page 14, lines 25-27). The results were expressed as mean IgG and IgA antibody titers in serum, wherein the results indicated an enhanced immune response by the antibodies, see Figure 2. Figure 3 teaches the kinetics of lymphocyte proliferation where the mice were injected with 30ug of a mutant version of ExtB (page 14, line 35- page 15 line 10). Williams et al., teach the injected amounts of ExtB are effective to enhance the level of the immune response. Figure 4 teaches that immunization with either pure or mutated ExtB caused an increased activation in B cells in the amount of 80ug/ml.

Thus Williams et al., teach the instantly claimed inventions.

Response to Arguments

7. Applicant's arguments filed December 5, 2006 have been fully considered but they are not persuasive.

The rejection of claims 38-39, 43-44 and 49 under 35 U.S.C. 102(b) as being anticipated by Williams et al., (WO 97/02045 published January 23, 1997) is maintained for reasons already of record.

Applicant respectfully submits that Williams fails to inherently disclose methods of claims 38-39, 43-45 and 49. Applicants assert that the claims specify that the enhancing of a lymphocyte mediated or immunoglobulin mediated immune response to a vaccine against an infectious disease must be performed in a subject in need thereof; and Williams does not teach each and every limitation of the claims.

However the claims recite "…wherein the enhancement is compared to a lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone, ….wherein the EtxB is free from whole toxin and is not linked to an antigen and co-administering the vaccine, thereby enhancing the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease compared to the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease after administration of the vaccine alone. Regarding the interpretive "wherein" and "thereby" clauses, it is noted that the clause does not recite any additional steps, but simply states a characterization or conclusion of the results of those administering and co-administering steps. Therefore the "wherein" and "thereby" clauses are not considered to further limit the method defined by the claim and has not been given weight in construing the claims. Therefore, applicants' arguments are not persuasive since Williams et al., clearly teach a method for enhancing the level of an immune response to a vaccine against an infectious agent in a mammalian subject just as required by the instant claims.

Claim Rejections - 35 USC § 102

8. Claims 38-44, 46-47, 49-52 and 54-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Hazama et al., (Immunology, 1993).

Claim 38 is drawn to a method of enhancing a lymphocyte mediated or immunoglobulin mediated immune response to a vaccine against an infectious disease, in a mammal in need thereof, wherein the enhancement is compared to a lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone, comprising administering to the mammal a therapeutically effective amount of *Escherichia coli* heat labile enterotoxin B subunit (EtxB), wherein the EtxB is free from whole toxin and is not linked to an antigen and co-administering the vaccine, thereby enhancing the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease compared to the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease after administration of the vaccine alone. Claim 39 is drawn to the EtxB increasing the levels of B and T cell lymphocyte response.

Claim 49 is drawn to a method of enhancing a B and T cell lymphocyte mediated or immunoglobulin mediated immune response to a vaccine against an infectious disease, in a mammal in need thereof, wherein the enhancement is compared to a lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone, comprising administering *Escherichia coli* heat labile enterotoxin B subunit (EtxB) in conjunction

with administration of an antigen associated with an infectious disease, wherein the EtxB is free from whole toxin and is not linked to the antigen, to the mammal in an amount which is effective to increase the mammalian subject's levels of B and T cell lymphocyte response to the antigen and co-administering the vaccine, thereby enhancing the B and T cell lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease compared to the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone.

Claim 54 is drawn to a method of generating a lymphocyte mediated or immunoglobulin mediated immune response, in a mammal in need thereof, comprising administering to the mammal a between 50 and 100 ug of Escherichia coli heat labile enterotoxin B subunit (EtxB), wherein the EtxB is free from whole toxin and an antigenic determinant, wherein the EtxB and antigenic determinant are not linked to form a single active agent. Claim 60 is drawn to a method of enhancing a B and T cell lymphocyte mediated or immunoglobulin mediated immune response, in a mammal in need thereof, comprising administering between 50 and 100 ug of *Escherichia coli* heat labile enterotoxin B subunit (EtxB) in conjunction with administration of an antigenic determinant associated with an infectious disease, wherein the EtxB is free from whole toxin and is not linked to the antigen, and wherein the EtxB and antigenic determinant are not linked to form a single active agent.

Claims 55 and 61are drawn to the EtxB and antigenic determinant are administered to the mammal in need thereof in multiple doses. Claims 40, 50, 57 and 62

are drawn to the antigen is a virus antigen from the herpes virus family. Claims 41, 51, 58 and 63 are drawn to the virus antigen being selected from the group consisting of Herpes Simplex Virus- 1 (HSV- 1), Herpes Simplex Virus-2 (HSV-2), Epstein-Barr Virus (EBV), Varicella-zoster Virus (VZV), Cytomegalovirus (CMV), Human Herpes Virus-6 (HHV-6), Human Herpes Virus-7 (HHV-7) and Human Herpes Virus-8 (HHV-8). Claims 42, 52, 59 and 64 are drawn to the virus antigen being selected from the group consisting of HSV- 1, HSV-2, CMV or EBV. Claims 43 and 46 are drawn to the vaccine being an antigen. Claims 44, 47 and 56 are drawn to the EtxB and antigen being administered to the said mammalian subject in an amount which is effective to increase the mammalian subject's levels of B and T cell lymphocyte response to the antigen.

Hazama et al., teach that the non-toxic B subunit (LTB) of the heat labile toxin produced by enterotoxigenic *Escherichia coli* has been expected to potentiate local IgA antibody response to co-administered foreign antigens (page 643 para. 2). The LTB of Hazama et al., is same B subunit of the heat labile *Escherichia coli* enterotoxin referred to by the instant claims as ExtB. In this study Hazama et al., created a recombinant LTB (ExtB) and investigated the mouse mucosal and systemic immune response elicited by intranasal immunization with several forms of a recombinant viral antigen (page 644, para. 2). These immunizations included the use of truncated Herpes Simplex Virus Type 1 (HSV-1) glycoprotein D (t-gD) being co-administered with LTB (page 644, para. 2). Hazama et al., teach administering to the mammalian mouse subject an effective amount of the LTB wherein the LTB is free from whole toxin and not linked to an antigen. Hazama et al., teach co-administration. Hazama et al., also teach the

measurement of the antibody response, see Table 1 (page 646), which shows the administration of effective amounts of LTB alone and the co-administration of t-gD and LTB. The LTB by itself exhibited high immunogenicity when administered (page 647, para. 2). Table 2, at page 646, shows protection against a HSV-1 challenge in mice while table 4 shows protective immunity against HSV systemic infection in mice. . However Table 2 is show that truncated glycoproteinD of HSV-1 co-administered with interleukin 2 (IL-2) and Table 4 shows t-gD linked EtxB. Table 1 clearly shows the co-administration of an HSV-1 antigen and the EtxB is free from whole toxin and not linked to an antigen. The glycoproteins of HSV are vaccines against HSV-1 infectious agents, see the instant specification at example 1 (pages 33-34), example 4 (page 35), and example 7 (pages 36-37) which teach that these same HSV-1 glycoproteins are vaccines against HSV infections. Hazama teach mucosal and systemic antibody, i.e, immunoglobulin mediated immune response elicited by immunization. Hazama et al., teaches separate proteins and co-administration and states that tgD-LTB co administered with LTB produced a 10-fold level higher level of serum antibodies (page 648).

Therefore Hazama et al., teach the instant claims.

Response to Arguments

9. The rejection of claims 38-44, 46-47 and 49-52 under 35 U.S.C. 102(b) as being anticipated by Hazama et al., (Immunology, 1993) is maintained for reasons already of record.

Applicants' assert that the tg-D is not a vaccine, However the claims are drawn to a method of enhancing a lymphocyte mediated or immunoglobulin mediated immune response to a vaccine against an infectious disease, comprising administering to the mammal a therapeutically effective amount of *Escherichia coli* heat labile enterotoxin B subunit (EtxB), wherein the EtxB is free from whole toxin and is not linked to an antigen and co-administering the vaccine. The claims also state that the vaccine is an antigen. An antigen is defined as a molecule that sometimes stimulates an immune response. Thus, all the molecules of Hazama et al., meet the limitations of the claims. Furthermore, the claims and specification teach that the antigen is from the herpes family, there are not other limitations on the antigen. Thus the antigen of Hazama et al., meet the limitations of the claims. Thus applicants' arguments are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 38-44, 46-47 and 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Neither the specification nor originally presented claims provides support for a method of enhancing a lymphocyte mediated or immunoglobulin mediated immune response to a vaccine against an infectious disease, in a mammal in need thereof, wherein the enhancement is compared to a lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone, comprising administering to the mammal a therapeutically effective amount of *Escherichia coli* heat labile enterotoxin B subunit (EtxB), wherein the EtxB is free from whole toxin and is not linked to an antigen and co-administering the vaccine, thereby enhancing the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease compared to the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease after administration of the vaccine alone.

Furthermore, neither the specification nor originally presented claims provides support for a method of enhancing a B and T cell lymphocyte mediated or immunoglobulin mediated immune response to a vaccine against an infectious

disease, in a mammal in need thereof, wherein the enhancement is compared to a lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone, comprising administering *Escherichia coli* heat labile enterotoxin B subunit (EtxB) in conjunction with administration of an antigen associated with an infectious disease, wherein the EtxB is free from whole toxin and is not linked to the antigen, to the mammal in an amount which is effective to increase the mammalian subject's levels of B and T cell lymphocyte response to the antigen and co-administering the vaccine, thereby enhancing the B and T cell lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease compared to the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against the infectious disease after administration of the vaccine alone, as required by the instant claims.

Applicant did not point to support in the specification for the newly claimed methods. Thus, there appears to be no teaching of a method for enhancing the level of a leukocyte mediated immune response to a vaccine against an infectious agent.

Applicant has pointed to support for the amendments to claims 38 and 49 at page 3, lines 15-19 and 34-36, page 31, lines 26-36, page 32, lines 8-13, page 35, lines 21-26, page 37, lines 5-13, page 39, lines 26-33 and Figures 9 and 11 of the instant specification. However page 3 does not teach enhancing the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease compared to the lymphocyte mediated or immunoglobulin mediated immune

response to the vaccine against an infectious disease after administration of the vaccine alone and co-administering the vaccine, thereby enhancing the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease compared to the lymphocyte mediated or immunoglobulin mediated immune response to the vaccine against an infectious disease after administration of the vaccine alone. It appears that the entire specification appears to fail to recite support for the newly recited method of enhancement. Therefore, it appears that there is no support in the specification. Therefore, applicants must specifically point to page and line number for support. Therefore, the claims incorporate new matter and are accordingly rejected.

New Grounds of Objection

Claim Objections

11. Claims 38 and 40-42 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

a) Claim 38 is drawn to administering to the mammal a therapeutically effective amount of *Escherichia coli* heat labile enterotoxin B subunit (EtxB), not linked to an antigen and co-administering the vaccine. However the claim does not administer an antigen.

b) Claims 40-42, 50-52, 57-59 and 62-64 are drawn to describing the antigen. However it is unclear how the type of antigen further limits the method steps of the

claims. There is no step that administers the antigen. Therefore clarification is required to overcome the objection.

Conclusion

12. No claims allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/

Primary Examiner, Art Unit 1645